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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,992	02/28/2002	Brian Reynolds	1001.1524102	8402

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EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,992	REYNOLDS ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50 and 52-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50 and 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05042004; 09132004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 3, 2004. The Examiner acknowledges the amendments to claims 5 (first occurrence), 35, 43, 47 and 54, as well as the cancellation of claims 5 (second occurrence) and 51. Claims 1-50 and 52-58 are currently pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 43-50, 52 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Rooney et al. ('105). Rooney et al. teach a guidewire including a core wire (20) having a proximal portion and a distal portion; a coil (30) having a proximal region and a distal region; and an outer structure disposed about at least a portion of the core wire and the coil. The core (20), including the distal portion thereof, may be formed of a linear elastic nickel titanium alloy (col. 3, lines 37-39). The proximal region of the coil is connected to the distal portion of the core wire and the distal region of the coil extending distally beyond the distal portion of the core wire (Fig. 2). The outer structure may be a polymer sheath (40) that extends distally beyond the distal

portion of the core wire and the distal region of the coil to form a tip. The outer structure may also include an outer coil disposed around the coil (col. 4, lines 1-13). The coils may be flat wire coils or round wire coils (col. 2, line 50). The coil may act as a safety structure. The core is wrapped around the entire length of the core which may include a tapered section (col. 3, lines 52-54). Although the coil is "preferably" not wrapped around the tapered core, this statement implies that the coil may be wrapped around the tapered core, in which case the coil would taper in a distal direction such that the coil would have a first outer diameter that differs from a second outer diameter.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-13, 16, 20-28, 30 and 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eder et al. (EP 0 806 220 A2) in view of Sahatjian et al. ('004).

Eder et al. teach a guidewire having a proximal section (176), a distal section (174)

formed of a superelastic nickel titanium alloy, and a connector (178) disposed about the proximal end of the distal section and the proximal end of the distal section. See Figure 5A and column 8, lines 2-18. Butt joints are illustrated in Figures 3 and 6. A connector material (156) is illustrated in Figure 3. A polymer sleeve is placed on the guidewire (col. 2, lines 5-10 and col. 5, lines 19-23). Eder et al. teach all of the limitations of the claims except that the distal section of the guidewire is formed of a linear elastic nickel titanium alloy.

Sahatjian et al. teach that linear elastic nickel titanium alloys and superelastic nickel titanium alloys are known to be interchangeable as materials for forming a core of a guidewire. Sahatjian et al. teach that linear elastic alloys are advantageous because it is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway (Abstract and col. 6, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the superelastic nickel titanium alloy distal section of a guidewire similar to that of Eder et al. of a linear elastic nickel titanium alloy as a design choice in view of the teachings of Sahatjian et al. in order to provide a guidewire that is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway.

6. Claims 14, 15, 17-19, 29, 31, 32, 54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eder et al. (EP 0 806 220 A2) in view of Sahatjian et al. ('004) as applied to claims 1, 12, 13, 16, 25, 28 and 30 above, and further in view of Gambale et al. ('959). Eder et al., as modified by Sahatjian et al. hereinabove, teach all of the limitations of the claims except

for the specifics of the coil; and therefore, do not disclose a flat ribbon, distally extending coil or an inner coil. However, Gambale et al teach that these features are well known in the art. See Figures1-5. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use coils similar to those of Gambale et al with the guidewire of Eder et al, since Eder et al., as modified by Sahatjian et al., teach a guidewire with a coil and Gambale et al disclose that such guidewire-coil configurations are advantageous in order to provide a guidewire with an atraumatic distal end.

7. Claims 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. ('025) in view of Eder et al. (EP 0 806 220 A2), and further in view of Sahatjian et al. ('004).

Richardson et al discloses guidewire with a polymer sheath that is disposed around at least a portion of a core and coil. The coil extends distally beyond the distal portion of the core wire. See Figs. 17, 20, 23, 26, 29 and 32. Richardson et al do not teach a connector. Eder et al disclose a guidewire comprising distal and proximal sections with a connector (178) disposed adjacent the ends for greater flexibility. See Fig 5A and col. 8, 11. 2-18. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Richardson et al with the connector of Eder et al to achieve greater flexibility. The distal sections of both the core wires of Richardson et al. and Eder et al. are formed of superelastic alloys rather than linear elastic nickel titanium alloys as claimed.

Sahatjian et al. teach that linear elastic nickel titanium alloys and superelastic nickel titanium alloys are known to be interchangeable as materials for forming a core of a guidewire.

Sahatjian et al. teach that linear elastic alloys are advantageous because it is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway (Abstract and col. 6, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the superelastic nickel titanium alloy distal section of a guidewire similar to that of Richardson et al., as modified by Eder et al. hereinabove, of a linear elastic nickel titanium alloy as a design choice in view of the teachings of Sahatjian et al. in order to provide a guidewire that is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway.

8. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. in view of Eder et al. and Sahatjian et al. as applied to claim 54 above, and futher in view of Sepetka et al. ('047). Richardson et al., as modified by Eder et al. and Sahatjian et al. hereinabove, teach a guidewire as recited for claim 54. The combination does not teach a flat wire coil. Sepetka et al. teach a flat wire coil for better attachment to the distal end of the core. See col. 6, lines 10-18 and Figure 1. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Richardson et al, Eder et al, and Sahatjian et al. with the flat wire coil of Sepetka et al. for better attachment of the coil to the core.

Response to Arguments

9. Applicant's arguments with respect to claims 1-58 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Eder et al.; Richardson et al.; Gambale et al.; Sepetka et al. and Morrison et al. all fail to teach or suggest a guidewire having at least a distal section formed of linear elastic nickel titanium alloy. This argument is moot in view of the new grounds of rejection, citing at least one of Rooney et al. and Sahatjian et al., set forth hereinabove.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abrams et al. ('570) teach a superelastic guiding member including a proximal section, a distal section and a connector therebetween. Eder et al. ('637) teach a composite guidewire including a proximal section, a distal section and a connector therebetween. Rooney et al. ('599) teach a guidewire having a core that is formed of either a superelastic nickel titanium alloy or a linear elastic nickel titanium alloy.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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November 23, 2004